REMARKS

Reconsideration of the present application is requested. Applicant appreciates the indication of allowance of claims 54-65 and 69-72. New claims 93-96 have been added which depend from claim 80. In view of the following arguments, it is believed all of the pending claims are in condition for allowance.

Claims 34-40, 42-47, 49, 51-53 and 80-92 had been previously indicated to be allowable, but this indication of allowability was withdrawn in the face of a rejection under 35 U.S.C. 102(b) based on U.S. Patent No. 6,506,214 to Gross (the '214 Patent). It is well-decided that anticipation requires that the cited reference disclose each and every feature of the claimed invention either explicitly or inherently. See, *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1375, 81 U.S.P.Q.2d 1324 (Fed. Cir. 2006). With respect to method or process claims, the principles of inherency apply to a prior art device only if "the prior art device, in its normal and usual operation, would necessarily perform the method claimed." M.P.E.P. 2112.02. The '214 Patent is not anticipatory of any of the pending claims because it fails to disclose expressly or inherently each and every claimed element.

Clear errors have occurred in the anticipation rejection under the '214 Patent of the independent claims 45, 80 and 92. Claim 45 recites a method of restoring disc height. It is not clear whether the recited steps in this method claim were fully considered when the '214 Patent was applied as an anticipatory reference. The rejection includes a statement that recitation of intended use must result in a structural difference. See, p. 3, ll. 3-5 of Office Action. However, the method claims are not device claims and "structural differences" are not germane to the patentability of a method claim. In order of for the '214 Patent to anticipate claim 45, it must explicitly or inherently disclose each step recited in that claim. The first step is "creating an opening through the disc annulus fibrosus in communication with the intradiscal space." The '214 Patent only discloses cementing a polyethylene liner to the face of the glenoid vault, a bony structure in the shoulder against which the end of the humerus bears. The vault 10 and humerus 18 are depicted in FIG. 3 of the '214 Patent. This is not the spine, or the intradiscal space, or the spinal disc. The '214 Patent does not disclose or contemplate any device or procedure that is used in the spine or a spinal disc. Whether the tube 22 of the '214 Patent could be

jammed into the spine of a patient does not make the '214 Patent anticipatory of claim 45, any more than a patent to a pointed stick or crowbar that could also be jammed into the spine. The '214 Patent simply does not disclose creating an opening in the spinal disc, as required in the first step of claim 45.

The next step calls for distracting the vertebral bodies apart. Again, the '214 Patent only discloses a shoulder procedure so it clearly does not disclose distracting vertebral bodies. Moreover, there is no discussion of distracting anything in the '214 Patent. The '214 Patent only discloses a procedure for placing a liner on a bearing surface of a bone, facilitated by a "vacuum cleaner" procedure performed inside the glenoid cavity. There is nothing to distract in the procedure disclosed in the '214 Patent. It was suggested that the bent tip 26 of the suction tube 22 in the '214 Patent "is capable of distracting upon insertion". There is nothing in the '214 Patent that suggests that the tip is strong enough or used in any way to perform any distraction anywhere, let alone in the spine where significant distraction forces are required to separate adjacent vertebrae. This statement with respect to the tip of the suction tube is no different than pointing to a crowbar patent and claiming that the crowbar is capable of distracting the spine.

The next step calls for introducing a curable biomaterial under pressure through the opening in the disc annulus fibrosus into the intradiscal space in which the biomaterial has properties "substitutive of the nucleus pulposus." The '214 Patent fails on every level with respect to this limitation of claim 45. First, as explained above, the '214 Patent only discloses a shoulder procedure, not a procedure occurring in the spine. Thus, there is no opening to an intradiscal space explicitly or inherently disclosed in the '214 Patent. Second, the bone cement disclosed in the '214 Patent is definitely not "substitutive of nucleus pulposus". Third, the suction tube 22 of the '214 Patent is not used to introduce anything into the glenoid cavity, let alone a fluent material or a curable biomaterial. The tube 22 is simply a vacuum cleaner to remove debris and excess fluid from the glenoid cavity and help draw bone cement onto the glenoid vault. Col. 3, ll. 7-25. The vacuum is continuously maintained in the tube 22 to apply a suction force through the honeycomb structure of the cancellous bone in the glenoid vault. Col. 3, ll. 18-21. When the vacuum is no longer needed, the suction tube 22 is removed. There is no disclosure in the '214 Patent of the tube 22 being used to introduce material into the

glenoid cavity, and this would in fact completely frustrate the express purpose of the invention of the '214 Patent, namely to clean out the cavity and provide a clean, dry surface to receive bone cement.

Since the '214 Patent does not disclose introducing anything through the tube 22, it clearly does not disclose introducing a material under pressure, as set forth in claim 45. The final step in claim 45 calls for maintaining the seal and the pressure until the biomaterial is cured. Since there is no pressurized injection through the tube 22, the '214 Patent cannot disclose maintaining that pressure for any purpose.

The use of the '214 Patent as anticipatory to Applicant's claim 45 is wholly improper. No step recited in claim 45 is disclosed in the '214 Patent. Moreover, the method steps of claim 45 have no application to the shoulder procedure described in the '214 Patent. Thus, there can be no fallback position that the procedure disclosed in the '214 Patent could be used in the spine. The only aspect of the '214 Patent that was cited in the Office Action as providing any link to Applicant's inventive method of claim 45 is that the tube 22 could somehow be used to perform some of the steps recited in this claim. As demonstrated above, even if this extremely tenuous link is accepted, the device of the '214 Patent when used as disclosed in that patent still does not satisfy the limitations of claim 45. The allegation that the '214 Patent anticipates claim 45 (or any other claim) of the present application is based only on the prohibited application of hindsight to the claimed invention.

Independent claim 92 is another method claim. Many steps of this claim are similar to the steps in claim 45, so the discussion regarding the inapplicability of the '214 Patent applies with equal force. Moreover, claim 92 recites the additional step of removing at least a portion of the nucleus pulposus. Of course, the nucleus pulposus is the functional component of the intravertebral disc that allows the spine to bend and exert force. The '214 Patent certainly does not disclose removing any part of the spine since that patent only concerns a procedure on the glenoid vault. Moreover, the '214 Patent does not disclose or contemplate removing any functional part of the shoulder joint. The tube 22 is used to vacuum out "debris" occupying that glenoid cavity. Col. 1, ll. 44-46; col. 3, ll. 13-15. Claim 92 also calls for injecting a fluent curable material to replace the

removed functional component, the nucleus pulposus. The '214 Patent definitely does not want to replace the debris that is removed by the suction tube.

Like method claim 45, none of the steps of method claim 92 can be found, either explicitly or inherently, in the '214 Patent. The '214 Patent is only concerned with providing a clean and dry surface to receive bone cement to glue a liner onto the face of the glenoid vault. There is no reason for the procedure disclosed in the '214 Patent to incorporate any of the steps of Applicant's inventive method. Similarly, there is no aspect of the procedure disclosed in the '214 Patent that is applicable to the spinal procedure of Applicant's invention. The '214 Patent simply cannot anticipate claim 92.

Independent claim 80 recites a kit of parts that includes a tube adapted to be received in an opening in the annulus fibrosus with a seal for sealing that opening as a curable fluent material is introduced therethrough into the disc space. The fluent material is required upon curing to have "properties substitutive of the nucleus pulposus." As expressed at length above, the '214 Patent bears no relation to spinal procedures and does not contemplate a biomaterial that is a substitute or the disc nucleus pulposus. The '214 Patent only discloses bone cement that is as different from a substitute nucleus material as possible. The reference to col. 3, lines 1-27 of the '214 Patent is of no help – there is no discussion in this excerpt of the properties of the cement, other than it adheres to the face of the glenoid vault (col. 3, ll. 15-16). The curable fluent material in Applicant's claim 80 is not intended to glue the spine together, so the discussion of the bone cement in the '214 Patent is immaterial to the present invention.

The extent of the failure of the '214 Patent under 35 U.S.C. 102(b), as well as the inappropriateness of the present anticipation rejection, is even more apparent when considering some of the dependent claims. For instance, the following dependent claims were said to be anticipated by the '214 Patent, even though nothing close to the recited limitations can be found in the '214 Patent:

Claim 34 - "said fluent material is introduced through a tube." In the '214 Patent, no fluent material is introduced through the tube 22 – only blood, fluids and debris are withdrawn from the glenoid vault. Col. 1, ll. 44-46; col. 3, ll. 7-16.

Claim 37 – "further including the step of placing a cannula having a lumen … and inserting said tube through said lumen." The '214 Patent only discloses one tube 22. No separate cannula is disclosed or contemplated in the '214 Patent.

Claim 38 – "said seal is disposed in said lumen." Since the '214 Patent fails to disclose a cannula with a lumen, it certainly cannot disclose a seal disposed in that non-existent lumen.

Claim 39 – "wherein said cannula is configured to distract two vertebrae." Again, since the '214 Patent fails to disclose a separate cannula, that non-existent cannula cannot distract anything. Moreover, the '214 Patent does not disclose a procedure involving the spine or vertebral space, but only a procedure for cementing a liner onto the face of the glenoid cavity (i.e., the shoulder).

Claim 43 – "providing a vent." There is no vent disclosed in the '214 Patent, nor would a vent be appropriate since it would defeat the suction applied through the tube 22. Col. 3, ll. 18-21.

Claim 44 – "the biomaterial is introduced … until the biomaterial seeps from said vent." Since the '214 Patent does not disclose a vent, there is nothing for any biomaterial to seep through.

Claim 46 – "further including the step of removing at least a portion of the nucleus pulposus of the disc." Since the '214 Patent only concerns a procedure on the bones of the shoulder, it does not disclose any structure of the spine, and certainly does not disclose the spinal disc, its nucleus pulposus or the removal of some part of the nucleus pulposus. Moreover, the tube 22 in the '214 Patent is not used to remove anything other than debris contained within the glenoid cavity 16 to provide a drier surface in the glenoid vault 19. Col. 1, ll. 44-46; col. 3, ll. 7-18.

Claim 47 – "removing substantially all of the nucleus pulposus." Since the '214 Patent bears no relation to the spine, it cannot disclose or contemplate removing all of a spinal disc nucleus.

Claim 52 – "the distraction step is performed by a separate distractor." The '214 Patent does not disclose distracting anything, nor is distraction necessary to prepare the glenoid vault to receive a glued-on liner. Even if the bent tip 26 of the tube 22 can

somehow be regarded as capable of distracting, it is certainly not a "separate distractor" as required by claim 52.

Claim 53 – "said distractor is a cannulated distractor." Since the '214 Patent does not disclose a separate distractor, it cannot disclose a cannulated distractor.

Claim 83 – "further including a vent adjacent said tube." As explained with respect to claim 43, the '214 Patent does not disclose a vent.

Claim 84 – "said fluent material is a curable biomaterial selected from the group of nucleus pulposus substitutes." The '214 Patent only discloses a cement capable of bonding a polyethylene liner to the face of the glenoid vault. Col. 1, ll. 29-30, 46-50, 65-68. The only cement disclosed is methyl-methacrylate, which is a common bone cement that hardens to a solid mass similar to bone. A nucleus pulposus is not a solid hard mass, otherwise the spine would be incapable of movement. Biomaterials that are "nucleus pulposus substitutes", therefore, do not cure into a solid hard mass, like bone cement. The differences between the claimed "nucleus pulposus substitutes" and the bone cement disclosed in the '214 Patent are profound and fundamental. Nothing in the '214 Patent discloses or contemplates the spine, the spinal disc, the nucleus pulposus or substitutes therefor.

Claim 87 – "the distal tip is removable from said tube." The tip 26 of the tube 22 in the '214 Patent is simply a bent portion of the tube. Col. 2, ll. 38-40. There is nothing in the '214 Patent to suggest that the tip 26 is removable from the rest of the integral tube 22.

Claim 88 – "a plurality of removable distal tips." Again, since the '214 Patent does not disclose a removable tip, it cannot disclose a selection of removable tips. Moreover, since the tip 26 of the tube 22 in the '214 Patent is only intended to suck up debris within the glenoid cavity, there is no need to change tips.

Claim 89 – "said distal tip is formed of a bioresorbable material." Since the tube 22, including its tip 26, is removed from the glenoid cavity (col. 3, ll. 24-25), there is no reason for it to be bioresorbable, and the '214 Patent understandably does not disclose this characteristic.

Claim 90 – "a syringe adapted to inject said fluent material." In the Office Action, reference was made to "an injection device, which is a syringe (FIG. 1)."

However, nowhere in the '214 Patent is any type of injection device depicted or described. The device shown in FIG. 1 is clearly not a syringe. Nor would a syringe be disclosed in the '214 Patent since the tube 22 is intended to provide continuous suction to the glenoid cavity. Col. 2, ll. 45-46.

The limitations in at least these sixteen dependent claims are not explicitly or inherently disclosed in the '214 Patent. At a minimum, the anticipation rejections of these sixteen claims are improper and further place in doubt the appropriateness of the citation of the '214 Patent in this Office Action.

At best, the '214 Patent discloses a tube with a seal on it that is used in a medical procedure. This is not enough to render the '214 Patent anticipatory to any of the claims of the present application. As explained in detail above, the '214 Patent fails to explicitly or inherently disclose each and every limitation of Applicant's claims. It is only through the use of impermissible hindsight that any connection whatsoever, no matter how remote, can be drawn between the '214 Patent and Applicant's claimed invention.

It is requested that the rejection of claims 34-40, 42-47, 49, 51-53 and 80-92 be withdrawn. It is believed that these claims are allowable over the art of record. Action toward a Notice of Allowance is earnestly solicited.

Respectfully submitted,

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